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510(k) Summary
21 CFR 807.92

JUN 2 7 2013

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

1. Submitter Information:

Applicant:	SenoRx, Inc. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-638-2954
Fax:	480-449-2546
Contact:	Sarah McCartney, Regulatory Affairs Associate
Date:	June 05, 2013

2. Subject Device:

Device Trade Name:	**StarchMark® Breast Tissue Marker** **StarchMark UltraCor™ Breast Tissue Marker**
Common or Usual Name:	Tissue Marker
Classification:	Class II
Classification Name:	Marker, Radiographic, Implantable (Product Code NEU)
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4300 (Implantable Clip)

3. Predicate Device:

StarchMark® Breast Tissue Marker (K081085; cleared August 1, 2008)

4. Summary of Change:

A statement regarding allergic reactions was moved from the warnings section to the contraindications section of product labeling. Additional updates to other sections of the IFU are also being implemented through this submission.

5. Device Description:

StarchMark® Breast Tissue Marker

The StarchMark® Breast Tissue Marker is a sterile, single use device, comprised of a disposable applicator and an implantable marker. The marker contains six polysaccharide (starch) pellets and one polylactic/polyglycolic acid-based copolymer (PLA/PGA) pellet which are essentially resorbed by the body after approximately 2 weeks. The polysaccharide pellets absorb body fluids to help in the control and management of bleeding. The PLA/PGA pellet contains a Stainless Steel Ribbon or "V" shaped wireform. The wireform is intended for long-term radiographic marking of the biopsy site. The StarchMark® Breast Tissue Marker is intended for breast tissue marking during a breast biopsy procedure.

StarchMark UltraCor™ Breast Tissue Marker

The StarchMark UltraCor™ Breast Tissue Marker is a sterile, single use device, comprised of a disposable applicator and an implantable marker. The marker contains four polysaccharide (starch) pellets and one polyethylene glycol (PEG) pellet which are essentially resorbed by the body after approximately 2 weeks. The polysaccharide pellets absorb body fluids to help in the control and management of bleeding. The PEG pellet contains a Stainless Steel "V" shaped wireform. The wireform is intended for long-term radiographic marking of the biopsy site. The StarchMark UltraCor™ Breast Tissue Marker is intended for breast tissue marking during a breast biopsy procedure.

6. Indications for Use of Device:

The StarchMark® Breast Tissue Marker is intended to radiographically mark breast tissue during a percutaneous breast biopsy procedure.

7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject device are substantially equivalent to those of the predicate device, in terms of following:

- Intended use
- Indications for use
- Target population
- Fundamental scientific technology

- Operating principle
- Implant design and materials
- Applicator design and materials
- Performance specifications
- Packaging configuration
- Sterility assurance and method of sterilization

There are no changes to the design, materials, performance specifications, packaging or sterilization of the subject device compared to the current legally marketed predicate device. The only modification is to the labeling which is notably different in the following manner:

- Contraindications

8. Performance Testing Summary:

The change to contraindications described in this submission does not affect the design of the device and no new or increased risks have been identified, therefore additional bench performance testing was not warranted.

9. Conclusion:

The subject StarchMark® Breast Tissue Marker is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SenoRx, Inc
% Ms. Sarah McCartney
Regulatory Affairs Associate
1625 West 3rd Street
Tempe, Arizona 85281

June 27, 2013

Re: K131654
Trade/Device Name: StarchMark Breast Tissue Marker;
StarchMark Ultracor Breast Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: June 05, 2013
Received: June 06, 2013

Dear Ms. McCartney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR
Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131654

Device Name: StarchMark® Breast Tissue Marker
StarchMark UltraCor™ Breast Tissue Marker

Indications for Use: The Breast Tissue Marker is intended to radiographically mark breast tissue during a percutaneous breast biopsy procedure.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131654